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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/949,904	10/15/97	LAVALLIE	GI-5288R

EXAMINER: E

HM21/0429

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ART UNIT	PAPER NUMBER
1642	4

1642

DATE MAILED: 04/29/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on March 23, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days ~~month(s), or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-27 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 1-27 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1998-434-496/40517

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1, 3, 5, 7-10 and 14-17 are drawn to an isolated DNA consisting of nucleotides from SEQ ID NO:1, host cell and culture and a method of producing protein classified in Class 536, subclass 23.1, Class 435, Subclass 320.1 and Class 435, subclass 325.

Group II. Claims 2, 4, 6 and 16 are drawn to an isolated DNA consisting of nucleotides from SEQ ID NO:2, host cell, culture and a method of producing a protein, classified in Class 536, subclass 23.1, Class 435, Subclass 320.1 and Class 435, subclass 325.

Group III. Claims 11-13 are drawn to an isolated DNA further comprising a nucleotide sequence encoding a suitable signal peptide 5' to and linked in frame to the DNA coding sequence, a vector and a host cell transformed with the vector, classified in Class 536, subclass 23.1.

Group IV. Claims 18-20, 22, 23 and 25 are drawn to a purified polypeptide and composition, classified in Class 530 subclass 350.

Group V. Claim 21 is drawn to a method of altering the regulation of pancreatic genes classified in Class 514, subclass 2.

Group VI. Claim 24 is drawn to an antibody to SDF-5, SEQ ID NO:2, classified in Class 530, subclasses 387.1 and 389.1.

Group VII. Claim 26 is drawn to an antibody to SDF-5, SEQ ID NO. 3, classified in Class 530, subclasses 387.1 and 389.1.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written

Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and V-VII as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups I/II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (i) the process as claimed can be used to make other and materially different product or (ii) the product as claimed can be made by another and materially different process [see *MPEP* § **806.05(f)**]. In the instant case the product as claimed can be made by a materially different process such as non recombinant peptide synthesis techniques such as the Merrifield technique.

The inventions of Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed

can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups V and I-III and VI-VII are not at all related because the isolated DNAs and antibodies of Groups I-III and VI-VII are not used in the method of Group V.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising nucleotide sequences consisting of different lengths of SEQ ID NO:1 that therefore have distinct sequences and structures, one from the other, comprising nucleotides (a) 256-1140, (b) 307-1140, (c) 310-1140, (d) 313-1140, (e) 316-1140, (f) 319-1140, (g) 322-1140, (h) 325-1140, (i) 328-1140, (j) 256-1143, (k) 307-1143, (l) 310-1143, (m) 313-1143, (n) 316-1143, (o) 319-1143, (p) 322-1143, (q) 325-1143 and (r) 328-1143. If species (n) 316-1143 is elected, claims 7-10 and 17 will be examined. If species (j) 256-1143 is elected, claim 14 will be examined.

5. Group II is further subject to election of a single disclosed species.

Claim 2 is generic to a plurality of disclosed patentably distinct species comprising structurally different isolated DNA sequences comprising (a) SEQ ID NO: 2 and (b) SEQ ID NO:3. Species (a) is further subject to election of a single disclosed species because Species (a) is generic to a plurality of disclosed

patentably distinct species comprising nucleotide sequences consisting of different lengths of SEQ ID NO:2 that therefore have distinct sequences and structures, one from the other, comprising nucleotides (a) 1-295. (b) 18-295, (c) 19-295, (d) 20-295, (e) 21-295, (f) 22-295, (g) 23-295, (h) 24-295.

6. Group IV is further subject to election of a single disclosed species.

Claim 18 is generic to a plurality of disclosed patentably distinct species comprising structurally different purified polypeptides comprising an amino acid sequence according to (a) SEQ ID NO:2 and (b) SEQ ID NO:3. If Species (a) is elected claims 18, 19, 20 and 22 will be examined. If Species (b) is elected claims 18, 23 and 25 will be examined.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4065.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in

the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
April 27, 1998

LILA FEISEE
SUPERVISORY PATENT EXAMINER